K093425

SUMMARY OF SAFETY AND EFFECTIVENESS

February 16, 2010

FEB 24 2010

Trade Name: BaseSens I Blood Glucose Monitoring System

Common Name: Blood Glucose Monitoring System

Classification Name: System, Test, Blood Glucose, Over the Counter

Classification Panel: Clinical Chemistry

Applicant:

Eran Bashan, Ph.D.
President

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All questions and/or comments concerning this document should be made to:

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1.0 DESCRIPTION OF THE PRODUCT

The BaseSens I Blood Glucose Monitoring System is identical to the i-Sens CareSens N Blood Glucose Monitoring System. The Hygieia BaseSens I Blood Glucose Monitoring System is a rebranded CareSens N System. Rebranding here is intended to be understood as all components of the CareSens N System have been relabeled with the Hygieia name BaseSens I or BaseSens I Blood Glucose Monitoring System.

As fully identical to the i-Sens CareSens N Blood Glucose Monitoring System, the BaseSens I Blood Glucose Monitoring System is thereby substantially equivalent to the i-Sens CareSens N Blood Glucose Monitoring System.

1.1 The Hygieia, Inc. BaseSens I Blood Glucose Monitoring System

1.1.1 The System includes the BaseSens I blood glucose meter, test strips and controls.

Classification or descriptor	Name or designation
Trade Name	BaseSens I Blood Glucose Monitoring System
Common Name	Blood Glucose Monitoring System
Classification Name	System, Test, Blood Glucose, Over the Counter
Classification Panel	Chemistry
Product Code	NBW (also CGA and JJX)
Regulation Number	862.1345

2.0 PREDICATE DEVICES

2.1 i-Sens CareSens Blood Glucose Monitoring System K080923 and the CareSens N Blood Glucose Monitoring System (k083468) are manufactured by i-SENS, Seoul, South Korea.

2.1.1 The device under review is also manufactured by i-SENS, Seoul, South Korea. The BaseSens I Blood Glucose Monitoring System is a re-branding of the CareSens N System and is substantial equivalent to the CareSens N System.

3.0 INDICATIONS FOR USE

3.1 The BaseSens I Blood Glucose Monitoring System and the CareSens N System have the following indications for use.

BaseSens I Blood Glucose Monitoring System	CareSens N Blood Glucose Monitoring System
The BaseSens I Blood Glucose Monitoring System is used for the quantitative measurement of glucose levels in capillary whole blood as an aid in monitoring the effectiveness of diabetes management at home or in clinical settings. The BaseSens I Blood Glucose Monitoring System should be used only for testing outside the body	Same

(in vitro diagnostic use only). The BaseSens I Blood Glucose Monitoring System is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates. Testing sites include the fingertip along with alternate sites testing (AST) on the forearm, palm, thigh and calf. AST in this system can be used only during steady-state blood glucose conditions	
BaseSens I Test Strip is used with the BaseSens I Blood Glucose Meter for quantitatively measuring glucose in capillary whole blood. The BaseSens I Test Strip is intended for self-testing outside the body (in vitro diagnostic use only). The BaseSens I Test Strips are not intended for the diagnosis of or screening for diabetes mellitus, and are not intended for use on neonates. Testing sites include the fingertip along with alternate sites testing (AST) on the forearm, palm, thigh and calf. AST in this system can be used only during steady-state blood glucose conditions.	Same
BaseSens I Control A&B Solutions are red liquid to check that both the meters and test strips are working together properly. It contains a known range of glucose as written on the bottle.	Same.

4.0 DEVICE DESCRIPTIONS

4.1 Specifications

4.1.1 The BaseSens I Blood Glucose Monitoring System and the CareSens N Blood Glucose Monitoring System including the following identical system components.

4.1.1.1 BaseSens I Meter (included in the System package)

4.1.1.2 BaseSens I Test strips (included in the System package)

4.1.1.3 BaseSens I Control Solutions. The Control Solutions are not included in the System package. This component can be purchased separately.

4.1.2 The BaseSens I Blood Glucose Monitoring System and the CareSens N Blood Glucose Monitoring System have identical product specifications.

4.2 Materials

4.2.1 The components used in the manufacture of the BaseSens I meter are identical to those of the i-Sens CareSens N meter.

4.2.2 The components used in the manufacture of the BaseSens I test strips are identical to those of the i-Sens CareSens N test strips.

4.2.3 The components used in the manufacture of the BaseSens I control solution are identical to those of the i-Sens CareSens N control solution.

5.0 COMPARISON OF BASESENS SYSTEM AND ITS PREDICATES

Device Features			
Item	**BaseSens I BGMS**	**CareSens N BGMS**	**CareSens BGMS**
Enzyme	Glucose Oxidase	Glucose Oxidase	Glucose Oxidase
Measurement Principle	Amperometric method	Amperometric method	Amperometric method
Test Principle	Glucose oxidase chemical reaction. The instrument measures the extent of current cause by presence of glucose in sample.	Glucose oxidase chemical reaction. The instrument measures the extent of current cause by presence of glucose in sample.	Glucose oxidase chemical reaction. The instrument measures the extent of current cause by presence of glucose in sample.
Intended use	The test strips work with the device to quantitatively measure glucose in capillary whole blood. The test Strips are for *in vitro* (i.e., outside the body) diagnostic use only.	The test strips work with the device to quantitatively measure glucose in capillary whole blood. The test Strips are for *in vitro* (i.e., outside the body) diagnostic use only.	The test strips work with the device to quantitatively measure glucose in capillary whole blood. The test Strips are for *in vitro* (i.e., outside the body) diagnostic use only.
Sample	Fresh capillary whole blood	Fresh capillary whole blood	Fresh capillary whole blood
Electrode	Carbon	Carbon	Carbon
Calibration	Plasma-equivalent	Plasma-equivalent	Plasma-equivalent
Test Time (seconds)	5	5	5
Sample volume (µL)	0.5	0.5	0.5
Memory	250	250	250
Test Range(mg/dL)	20~600	20~600	20~600

Hematocrit range (%)	20~60 (below 400mg/dL)	20~60 (below 400mg/dL)	20~60 (below 400mg/dL)
Glucose units	Either mg/dL or mmol/L	Either mg/dL or mmol/L	Either mg/dL or mmol/L
Checking the system	Control solution	Control solution	Control solution
Alternate Site Capability	Yes	Yes	Yes
Operating Humidity	10~90%	10~90%	10~90%
Differences			
Item	BaseSens I BGMS	CareSens N BGMS	CareSens BGMS
Coding	Automatic code identification	Automatic code identification	Manual input by button
Self-diagnosis of code identification function	Yes	Yes	No
Three time set Alarms and 2-hour post-meal Alarm	Yes	Yes	No
Post-meal flagging	Yes	Yes	No
Number of buttons	3 buttons	3 buttons	2 buttons (CareSens II) 1 button (CareSens POP)

Conclusion: The BaseSens I Blood Glucose Monitoring System does not raise any new safety and efficacy concerns when compared to the cleared CareSens N Blood Glucose Monitoring System.

The BaseSens I Blood Glucose Monitoring System is identical to the i-Sens CareSens N Blood Glucose Monitoring System. The Hygieia BaseSens I Blood Glucose Monitoring System is a rebranded CareSens N Blood Glucose Monitoring System. As fully identical to the i-Sens CareSens N Blood Glucose Monitoring System, the BaseSens I Blood Glucose Monitoring System is thereby substantially equivalent to the i-Sens CareSens N Blood Glucose Monitoring System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

FEB 24 2010

Hygieia, Inc.
c/o Healthcare Technologies Consultants
Robert J. Bard, Esq.
Managing Director
P.O. Box 506
South Lyon, MI 48178

Re: k093475
Trade/Device Name: BaseSens I Blood Glucose Monitoring System
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW, CGA, JJX
Dated: January 17, 2010
Received: January 19, 2010

Dear Robert J. Bard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (k093475):

Device Name: BaseSens I Blood Glucose Monitoring System

Indication for Use: The BaseSens I Blood Glucose Monitoring System is used for the quantitative measurement of glucose levels in capillary whole blood as an aid in monitoring the effectiveness of diabetes management at home or in clinical settings. The BaseSens I Blood Glucose Monitoring System should be used only for testing outside the body (in vitro diagnostic use only). The BaseSens I Blood Glucose Monitoring System is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates. Testing sites include the fingertip along with alternate sites testing (AST) on the forearm, palm, thigh and calf. AST in this system can be used only during steady-state blood glucose conditions.

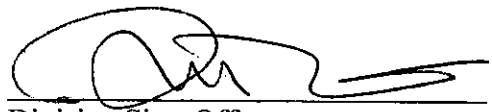
BaseSens I Test Strip is used with the BaseSens I Blood Glucose Meter for quantitatively measuring glucose in capillary whole blood. The BaseSens I Test Strip is intended for self-testing outside the body (in vitro diagnostic use only). The BaseSens I Test Strips are not intended for the diagnosis of or screening for diabetes mellitus, and are not intended for use on neonates. Testing sites include the fingertip along with alternate sites testing (AST) on the forearm, palm, thigh and calf. AST in this system can be used only during steady-state blood glucose conditions.

BaseSens I Control A&B Solutions are a red liquid to check that both the meters and test strips are working together properly. It contains a known range of glucose as written on the bottle.

Prescription Use ___x___ (21 CFR Part 801 Subpart D) and/or Over the Counter Use __x__ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)



Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k093475